

DADMAC HPV COMMITTEE

201-15208

1250 Connecticut Avenue, N.W. • Suite 700 • Washington, D.C. 20036  
Phone: 202-419-1500 • Fax: 202-659-8037

April 27, 2004

Administrator Michael O. Leavitt  
US Environmental Protection Agency  
P.O. Box 1473  
Merrifield, VA 22116  
Attention: Chemical Right-to-Know Program  
Via E-mail: [oppt.ncic@epa.gov](mailto:oppt.ncic@epa.gov) and [chem.rtk@epa.gov](mailto:chem.rtk@epa.gov)

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04 APR 29 PM 12:56

**Re: Submission of Test Plan and Robust Summaries for**  
**Diallyldimethylammonium chloride, CAS RN 7398-69-8**

Dear Administrator Leavitt:

The DADMAC HPV Committee is pleased to submit the attached test plan and robust summaries for diallyldimethylammonium chloride (DADMAC), CAS RN 7398-69-8, for the US HPV Challenge Program, AR-201.

In addition, please take this opportunity to update the HPV Challenge Summary Report (<http://www.epa.gov/chemrtk/smrestbl.htm>) to reflect that the sponsor for this chemical is the **DADMAC HPV Committee**, rather than the North American Polyelectrolyte Producers Association (NAPPA) as is currently listed.

Please do not hesitate to contact me at 202-419-1500 or [bobf@regnet.com](mailto:bobf@regnet.com) if I can provide any further clarification.

Sincerely,

Robert J. Fensterheim  
Executive Director

201-15208A

**Test Plan  
for  
Diallyldimethylammonium Chloride  
(DADMAC)**

**[CAS No. 7398-69-8]**

**DADMAC HPV COMMITTEE**

**c/o RegNet Environmental Services,  
1250 Connecticut Avenue, N.W., Suite 700,  
Washington, D.C. 20036**

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**Members of the Consortium:**

Ciba Specialty Chemicals Corporation.

Nalco Chemical Company

SNF Inc.

## Summary

The member companies of the Diallyldimethylammonium Chloride (DADMAC) Panel hereby submit for review and public comment their test plan for DADMAC under the Environmental Protection Agency's (EPA) High Production Volume (HPV) Challenge Program.

DADMAC (CAS No. 7398-69-8) is a monomer used in closed systems in the manufacture of water soluble cationic polymers used as coagulants. There is virtually no exposure to monomer in manufacturing or to polymer during use and the level of monomer in polymer is very low. This product has very low acute and chronic toxicity to experimental animals. There have been no reports of any deleterious effects after several decades of use in industry. DADMAC is not toxic to environmental organisms and is readily biodegradable.

We conclude that there is sufficient data on this intermediate and that no further testing is needed to safeguard human health. However, some testing is proposed to generate additional environmental data which we consider would be valuable.

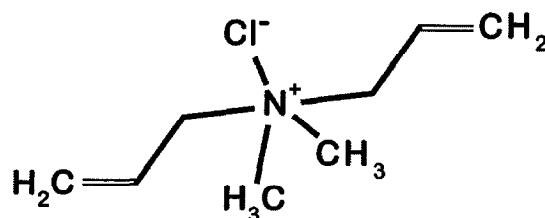
## Proposed Test Plan

1. Determination of the acute toxicity in Fathead Minnows (*Pimephales promelas*)
2. Determination of the acute toxicity in *Daphnia magna*
3. Determination of the inhibition in blue-green algae (*Subspicatus capricornutum*)

## Identity

Diallyldimethylammonium chloride (DADMAC) is a quaternary ammonium compound which has been manufactured in the United States for at least 40 years. It is the reaction product of allyl alcohol with dimethylamine. There are currently 3 manufacturing plants for DADMAC monomer in the United States. There is virtually no exposure to monomer during manufacture and emissions to air, water and soil are very low. The product is used almost exclusively as a monomer in the manufacture of cationic, water-soluble polymers which are used in such industries as water-treatment, paper-making and textile printing.

Its structure is shown below:



Diallyldimethylammonium chloride (DADMAC)

Only a small percentage of this monomer enters interstate commerce as most is polymerized on site either as a homopolymer or as a copolymer with acrylamide or other monomers in order to build molecular weight. Best available technology can drive monomer content in polymer down to 1% on an active polymer basis.

## Test Data

The test data available on DADMAC is given in the following table:

<b>Environmental Studies</b>
Safety Test in Blue Gill Sunfish
Effect on Soil Organisms
Anaerobic Aquatic Metabolism
Anaerobic Soil Metabolism
Effects of Microbes on Metabolism
Environmental Chemistry Studies
Leachability
Plant Availability
<b>Human Health Studies</b>
Acute Oral Administration in Rats (2)
Primary Skin Irritation (FHSA), Corrosivity (DOT), and Acute Eye Irritation (FHSA)
Segment I Multigeneration Study in Rats
Bacterial Reverse Mutation (Ames) Test (2)
<i>In vitro</i> Mammalian Cell Gene Mutation Test L5178Y TK+/- Mouse Lymphoma
<i>In vitro</i> Mammalian Chromosome Aberration Test in cultured Human Lymphocytes
Oral (Gavage) Rat Teratology
Oral Absorption, Distribution and Excretion Using C14 Labeled Monomer & Polymer
13 Weeks Oral Toxicity Feeding Study in Rats
13 Weeks Oral Toxicity Feeding Study in Dogs

## TOXICITY TO AQUATIC ORGANISMS

Tests Conducted on Aquatic Organisms			
Study	Species	Strain	Result
Acute Aquatic Toxicity (72h)	Fish	Blue Gill Sunfish	LC50 = 56 mg/l

The LC50 at 72 hours for Bluegill Sunfish (*Lepomis macrochirus*) is 56 mg/liter (Johnson, 1971). While DADMAC has not been tested in daphnia, other quaternized monomers used for manufacture of cationic polymers, have. The EC50 for daphnia for those substances is greater than 100 mg/liter. ECOSAR structure activity on DADMAC predicts fish, daphnid, and blue-green algae toxicity of 464, 28 and 33 mg/L respectively. An LC 50 in another native species, such as Fathead Minnow (*Pimephales promelas*), as well as test data for crustaceans, e.g., *Daphnia magna*, and algae e.g., *Subspicatus capricornutum*, would decrease uncertainty in this area. No further testing for health effects is proposed at this time. Evaluation of the acute toxicity of DADMAC to environmental organisms is consistent with the objectives of the EPA HPV Challenge Program.

## ENVIRONMENTAL FATE

Environmental Fate Studies	
Study	Result
Effect on Soil Organisms	No effect
Anaerobic Aquatic Metabolism	No effect
Effects of Microbes on Metabolism	No effect
Leachability	Mobile
Plant Availability	Low uptake

## ACUTE AND CHRONIC TOXICITY

Tests Conducted <i>In Vivo</i>			
Study	Species	Strain	Result
Acute Oral Toxicity	Rat	Sprague-Dawley	LD50 = 3030 mg/kg
Primary Skin Irritation	Rabbit	New Zealand White	Not irritating to skin
Corrosivity	Rabbit	New Zealand White	Not corrosive
Acute Eye Irritation	Rabbit	New Zealand White	Not irritating to eyes
Segment I Multigeneration	Rat	Sprague-Dawley	NOAEL = 1.25 mg/kg/day
Oral (Gavage) Teratology	Rat	Sprague-Dawley	NOAEL = 6.0 mg/kg/day
Oral Absorption, Distribution and Excretion	Rat	Not specified	Poorly absorbed
13 Weeks Oral Toxicity Feeding Study	Rat	Not specified	NOAEL = 50.0 mg/kg/day
13 Weeks Oral Toxicity Feeding Study	Dog	Beagle	NOAEL = 200.0 mg/kg/day
Mouse Micronucleus	Mouse	CD1	Negative
Tests Conducted <i>In Vitro</i>			
Study	Species	Strain	Result
Ames Test	Bacteria	<i>Salmonella t.</i>	Not mutagenic
Ames Test	Bacteria	<i>Salmonella t.</i>	Not mutagenic
Chromosome Aberration Test in Cultured Human Lymphocytes			Negative
Mammalian Cell Gene Mutation Test Mouse Lymphoma (L5178Y)			Negative

### **Acute Toxicity**

The acute oral rat LD50 for DADMAC is 3030 mg/kg (Sterner, 1975). DADMAC is non-irritating to rabbit skin and eyes. Since potential human exposure is very low, no further testing is for acute toxicity is proposed.

### **Mutagenicity**

DADMAC has been tested and found negative in the Ames test (San, 1991; de Jouffrey, 1996a), mouse lymphoma (L5178Y) (de Jouffrey, 1996b), and in human lymphocytes for chromosomal aberrations (de Jouffrey, 1996c). DADMAC has also been tested *in vivo* in the mouse micronucleus assay and found negative (Putnam, 1991). There was no mutagenic response in any of these tests. Based on these tests DADMAC is not considered to be mutagenic. No further testing for mutagenicity is proposed.

### **Repeated Dose Toxicity**

DADMAC has been tested in subchronic (13-week) feeding studies in rats and dogs. The NOAEL in rats was 50 mg/kg based on decreased body weight gain in the 500 mg/kg group (LOAEL) (Sterner, 1976). The NOAEL in dogs was 200 mg/kg based on decreased body weight gain in the 800 mg/kg group (Tegeris, 1976). No further subchronic toxicity tests are proposed as the NOAEL is 50 mg/kg. In addition, since DADMAC is clearly non-mutagenic, animal tests for carcinogenicity cannot be justified at this time.

### **Reproductive and Developmental Toxicity**

Teratology and reproduction studies have been performed on the homopolymer of DADMAC, polyDADMAC. This product contains systematically a significant residual amount of DADMAC monomer. With current, best-available technology, the lowest level of monomeric DADMAC that can be achieved during manufacture of this polymer is 1% by weight on a an active polymer basis. At the time these studies were conducted, the residual DADMAC in polyDADMAC was much higher, probably in the 3 to 5% range.

In the teratology study, there were no effects observed at the highest level of polymer tested, *i.e.*, 600 mg/kg. The animals were exposed to at least 6 mg/kg of DADMAC monomer per day (*i.e.*, 1% of 600 mg/kg/day) (Palmer, 1991). PolyDADMAC was tested



in a Segment I reproduction study (Adamik, 1979). The highest dose tested was 125 mg/kg. No effects were observed at this dose level. The animals were exposed to at least 1.25 mg/kg of DADMAC monomer per day. With a NOAEL in subchronic studies of 50 mg/kg/day and a NOAEL in the teratology study of 6 mg/kg/day, no further studies are proposed for reproductive or developmental toxicity. Furthermore, in the subchronic studies on rats and dogs, no adverse histological findings were reported in the reproductive system of either male or female animals.

### **Conclusion**

No further testing for health effects is necessary.

## **BACKGROUND INFORMATION: MANUFACTURING & APPLICATIONS**

### **Manufacturing**

DADMAC has been manufactured commercially for more than 40 years by the reaction of allyl chloride with dimethyl amine. This is carried out in a closed system since allyl chloride is irritating.

### **Commercial Application**

DADMAC is almost exclusively used in the manufacture of homo- and copolymers (the latter mainly with acrylamide). The concentration of residual monomer in these polymers is between 1 and 5% although current, best-available technology results in the majority of products containing around 1%. These polymers have been extensively tested for toxicity and are non-toxic. They are used in the water-treating, textile printing and paper manufacturing industries.

### **Shipping and Distribution**

Most of the polymers in the US are manufactured at the same site as the monomer is manufactured. Less than 25% of monomer in the US is shipped for polymerization elsewhere.

### **Worker/Consumer Exposure**

There is no significant consumer exposure to DADMAC. Worker exposure is very limited as both monomer and polymer manufacture are carried out in closed systems.

## REFERENCES

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Sterner, W. (1976). 13 Weeks Oral Toxicity Feeding Study with Monomer in Rats. International Bioresearch Laboratories, Hanover, Germany.

Tegeris, A. (1976). DADM: Ninety Day Feeding to Dogs. Pharmacopathics Reserach Laboratories, Laurel, MD.

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201-15208B

# I U C L I D

## Data Set

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<b>Existing Chemical</b>	: ID: 7398-69-8
<b>CAS No.</b>	: 7398-69-8
<b>TSCA Name</b>	: 2-Propen-1-aminium, <i>N,N</i> -dimethyl- <i>N</i> -2-propenyl-, chloride
<b>Structural formula</b>	: <chem>CH2=C2H3N.Cl.(CH3)2C2H3=CH2</chem>
<b>Molecular formula</b>	: C8H16N.Cl
<b>Molecular weight</b>	: 161.68
<b>Producer related part</b>	
<b>Company</b>	: DADMAC HPV Challenge Task Group
<b>Creation date</b>	: 27.10.2003
<b>Substance related part</b>	
<b>Company</b>	: DADMAC HPV Challenge Task Group
<b>Creation date</b>	: 27.10.2003
<b>Number of pages</b>	:
<b>Chapter (profile)</b>	: Chapter: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10
<b>Reliability (profile)</b>	: Reliability: without reliability, 1, 2, 3, 4

# 1. General Information

Id 7398-69-8

Date 27.10.2003

## 1.0.1 APPLICANT AND COMPANY INFORMATION

## 1.0.2 LOCATION OF PRODUCTION SITE, IMPORTER OR FORMULATOR

## 1.0.3 IDENTITY OF RECIPIENTS

## 1.0.4 DETAILS ON CATEGORY/TEMPLATE

### 1.1.0 SUBSTANCE IDENTIFICATION

#### 1.1.1 GENERAL SUBSTANCE INFORMATION

Substance type	: Organic
Physical status	: Solid
Purity	: > 99%.
Remark	: The commercial product is manufactured and shipped as a solution (60-70%) in water

#### 1.1.2 SPECTRA

## 1.2 SYNONYMS AND TRADENAMES

Diallyldimethylammonium chloride  
27.10.2003

Dimethyldiallylammonium chloride  
27.10.2003

*N,N*-Dimethyl-N-2-propenyl-2-propen-1-aminium chloride  
27.10.2003

DADMAC  
27.10.2003

DIMDAC  
27.10.2003

DMDAAC  
27.10.2003

# 1. General Information

Id 7398-69-8

Date 27.10.2003

## 1.3 IMPURITIES

Sodium chloride  
28.10.2003

## 1.4 ADDITIVES

## 1.5 TOTAL QUANTITY

### 1.6.1 LABELLING

No precautionary label is required  
28.10.2003

### 1.6.2 CLASSIFICATION

NFPA 1; 0; 0  
RCRA: not hazardous  
DOT: Not regulated  
28.10.2003

### 1.6.3 PACKAGING

## 1.7 USE PATTERN

Type	: Industrial
Category	: Chemical industry; used in synthesis of water soluble polymers, coagulants, retention aids.
Remark	: Commercial product is manufactured and shipped as a solution in water (60–70%).

28.10.2003

### 1.7.1 DETAILED USE PATTERN

### 1.7.2 METHODS OF MANUFACTURE

DADMAC is made by reaction of dimethylamine and allyl chloride.  
28.10.2003

# 1. General Information

Id 7398-69-8  
Date 27.10.2003

## 1.8 REGULATORY MEASURES

None.  
28.10.2003

## 1.8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES

None applicable.  
28.10.2003

## 1.8.2 ACCEPTABLE RESIDUES LEVELS

## 1.8.3 WATER POLLUTION

## 1.8.4 MAJOR ACCIDENT HAZARDS

## 1.8.5 AIR POLLUTION

## 1.8.6 LISTINGS E.G. CHEMICAL INVENTORIES

Listed on all major chemical inventories (TSCA, EINECS, AICS, ECL, etc.)  
28.10.2003

## 1.9.1 DEGRADATION/TRANSFORMATION PRODUCTS

## 1.9.2 COMPONENTS

## 1.10 SOURCE OF EXPOSURE

## 1.11 ADDITIONAL REMARKS

## 1.12 LAST LITERATURE SEARCH

## 1.13 REVIEWS



## 2. Physico-Chemical Data

Id 7398-69-8

Date 27.10.2003

### 2.1 MELTING POINT

Value : =133.02°C.  
Method : MPBPWIN v1.40.  
Year : 2003.  
GLP : No.  
Test substance : DADMAC (100% pure substance).  
Reliability : (2) valid with restrictions.  
Generally accepted method of calculation with restrictions.

29.10.2003

### 2.2 BOILING POINT

Value : =370.51°C  
Method : MPBPWIN v1.40 (adapted Stein & Brown method).  
Year : 2003.  
GLP : No.  
Test substance : DADMAC (100% pure substance).  
Reliability : (2) valid with restrictions.  
Generally accepted method of calculation with restrictions.

29.10.2003

### 2.3 DENSITY

Value : 1.03-1.05  
Method : Other: No data.  
Year : No data.  
GLP : No data.  
Test substance : DADMAC (70% pure substance).  
Reliability : (4) not assignable.  
Only short information available (safety data sheet).

29.10.2003

#### 2.3.1 GRANULOMETRY

Not applicable.  
28.10.2003

### 2.4 VAPOR PRESSURE

Value : =3.53 E-6 mm Hg at 25°C  
Method : MPBPWIN v1.40 (modified Grain method).  
Year : 2003.  
GLP : No.  
Test substance : DADMAC (100% pure substance).  
Reliability : (2) valid with restrictions.  
Generally accepted method of calculation with restrictions.

29.10.2003

## 2. Physico-Chemical Data

Id 7398-69-8

Date 27.10.2003

### 2.5 PARTITION COEFFICIENT

Partition coefficient : Octanol-water.  
log Pow : = -2.49  
Method : KOWWIN v1.66.  
Year : 2003  
GLP : No.  
Test substance : DADMAC (100% pure substance).  
Reliability : (2) valid with restrictions.  
Generally accepted method of calculation with restrictions.

29.10.2003

### 2.6.1 SOLUBILITY IN DIFFERENT MEDIA

Solubility in : Water.  
Value : 1E6 mg/l at 25°C.  
Method : WSKOW v1.40.  
GLP : No.  
Test substance : DADMAC (pure substance)  
Reliability : (2) valid with restrictions.  
Generally accepted method of calculation with restrictions. Additionally, no melting point equation was used

29.10.2003

Solubility in : Water.  
Value : Completely miscible.  
Method : Other: no data.  
GLP : No data.  
Test substance : DADMAC (pure substance)  
Reliability : (4) not assignable.  
Only short information available (safety data sheet).

29.10.2003

### 2.6.2 SURFACE TENSION

### 2.7 FLASH POINT

Value : Does not flash.  
Method : Other: no data.  
GLP : No data.  
Test substance : DADMAC (70% solution in water).  
Reliability : (4) not assignable.  
Only short information available (safety data sheet).

29.10.2003

### 2.8 AUTO FLAMMABILITY

Autoignition Temp. : >200°C.  
Method : Other: no data.  
GLP : No data.

## 2. Physico-Chemical Data

Id 7398-69-8

Date 27.10.2003

Test substance : DADMAC (70% solution in water).  
Reliability : (4) not assignable.  
Only short information available (safety data sheet).  
29.10.2003

### 2.9 FLAMMABILITY

### 2.10 EXPLOSIVE PROPERTIES

### 2.11 OXIDIZING PROPERTIES

### 2.12 DISSOCIATION CONSTANT

### 2.13 VISCOSITY

Value : 100 mPa.s  
Method : Other: no data.  
GLP : No data.  
Test substance : DADMAC (70%).  
Reliability : (4) not assignable.  
Only short information available (safety data sheet).  
28.10.2003

### 2.14 ADDITIONAL REMARKS

### 3. Environmental Fate and Pathways

Id 7398-69-8

Date 27.10.2003

#### 3.1.1 PHOTODEGRADATION

Type : Air.  
Method : AOPWIN v1.90.  
Year : 2003.  
GLP : No.  
Result : The atmospheric degradation behavior was assessed using AOPWIN (v. 1.90). An overall OH rate constant of  $72.5020 \text{ E-12 cm}^3/\text{molecule}\cdot\text{sec}$  was obtained. The following half-lives can be predicted under the chosen conditions:  
0.148 days (12h-day,  $1.5 \text{ E6 OH/cm}^3$ ); 1.770 hours.  
Overall ozone rate constant =  $2.400 \text{ E-17 cm}^3/\text{molecule}\cdot\text{sec}$ .  
Half-life = 0.477 days (at  $7 \text{ E11 mol/cm}^3$ ); 11.460 hours.  
Test substance : DADMAC (pure substance)  
Reliability : (2) valid with restrictions.  
Generally accepted method of calculation with restrictions.

29.10.2003

#### 3.1.2 STABILITY IN WATER

Type : Abiotic (hydrolysis).  
Method : HYDROWIN v1.67  
Year : 2003.  
GLP : No.  
Remark : Stable (model cannot estimate rate constant for this structure).  
Test substance : DADMAC (pure substance)  
Reliability : (2) valid with restrictions.  
Generally accepted method of calculation with restrictions.

29.10.2003

#### 3.1.3 STABILITY IN SOIL

#### 3.2.1 MONITORING DATA

#### 3.2.2 FIELD STUDIES

#### 3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Type : Volatility.  
Media : Water – air.  
Method : HENRYWIN v3.10.  
Year : 2003.  
Remark : The value obtained for Henry's constant was calculated as:  
Bond contribution method:  $7.20 \text{ E-12 atm}\cdot\text{m}^3/\text{mole}$  (group contribution calculation incomplete). According to Thomas (1990), the substance may be considered as "not volatile from water".  
Henry's LC (VP/WSol estimate using EPI values) =  $7.510 \text{ E-13 atm}\cdot\text{m}^3/\text{mole}$

### 3. Environmental Fate and Pathways

Id 7398-69-8

Date 27.10.2003

**Test substance** : DADMAC (pure substance)  
**Reliability** : (2) valid with restrictions.  
Generally accepted method of calculation with restrictions.

29.10.2003

**Type** : Level III Fugacity Model  
**Media** : Water – air – soil – sediment.  
**Method** : BCFWIN v2.14.  
**Year** : 2003.  
**Result** : The value obtained from the Level III Fugacity Model are as follows:

	Mass Amount (%)	Half-Life (hr)	Emissions (kg/hr)
Air	2.38 E-4	2.7	1000
Water	45.3	360	1000
Soil	54.6	360	1000
Sediment	0.0755	1.44 E3	0

Persistence time = 421 hours.

**Conclusion** : Regardless of the media to which DADMAC is released, virtually all, at steady state, is in the soil and water phases. Using the default emissions of equal amounts to soil, air, water and sediment (1000 kg/hr for each) the Level III model predicts that the distribution of DADMAC will be 54.6% in soil, 45.3% in water, <0.1% in sediment, and virtually nothing in air.

**Test substance** : DADMAC (pure substance)  
**Reliability** : (2) valid with restrictions.  
Generally accepted method of calculation with restrictions.

29.10.2003

#### 3.3.2 DISTRIBUTION

**Media** : Air – biota – sediment(s) – soil – water.  
**Method** : Calculation according to Mackay, Level 1.  
**Year** : No data.  
**Remark** : The following parameters were employed in this calculation:  
Vapor pressure: 1.8 E-5 Pa (20°C) (calculated);  
Molecular weight: 207.7 g/mol;  
water solubility: ca. 6000 g/l (20°C) (calculated);  
logPow: -2.55 (25°C) (calculated).  
**Result** : The following environmental distribution was predicted:  
water: ca. 100%; other environmental compartments below 0.001%.  
**Test substance** : DADMAC (pure substance)  
**Reliability** : (2) valid with restrictions.  
Generally accepted method of calculation with restrictions.

29.10.2003

#### 3.4 MODE OF DEGRADATION IN ACTUAL USE

#### 3.5 BIODEGRADATION

**Type** : Anaerobic soil metabolism  
**Reference** : Reick, 1980a  
**Soil** : Monongahela sandy loam soil

### 3. Environmental Fate and Pathways

Id 7398-69-8

Date 27.10.2003

**Concentration** : DADMAC (75% active;  $2 \times 10^6$  DPM (93.3  $\mu$ Ci)  
**Contact time** : 0, 28, 56, 84 days  
**Degradation** : = 0% after 28 day(s)  
**Year** : 1980  
**Method** : Monongahela sandy loam soil was oven-dried and 50 grams/flask used. Flasks were purged with nitrogen and sealed. After 45 days, half were purged again and half were flooded with 5 cc water. C14 radio-labeled DADMAC (75% active;  $2 \times 10^6$  DPM (93.3  $\mu$ Ci) was added to each flask. Four replicate flasks from each treatment group were removed after 0, 28, 56 and 84 days. Flasks were extracted with  $\text{CaSO}_4$  and methanol and the methanol filtered. Radioactivity in the methanol was determined in a liquid scintillation spectrometer. Another aliquot was chromatographed by TLC to determine DADMAC.

**Results** The results are summarized in the following table:

Days of anaerobic conditions	Non-Extractable Radioactivity (DPMX10 <sup>5</sup> /50 gm soil)		Extractable Radioactivity (DPMX10 <sup>5</sup> /50 gm soil)	
	Nitrogen Atmosphere	Flooded	Nitrogen Atmosphere	Flooded
0	5.9	5.9	1.3	1.3
28	6.1	6.1	1.3	1.3
56	6.1	6.2	1.2	1.2
84	6.2	6.2	1.1	1.2

**Test substance** : 14C-DADMAC (75% active)  
**Conclusion** : DADMAC is not anaerobically degraded  
**Reliability** : (2) valid with restrictions  
Acceptable, well documented report which meets basic scientific principles.

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(1)

**Type** : Anaerobic aquatic metabolism  
**Reference** : Reick, 1980b  
**Soil** : Monongahela sandy loam soil  
**Concentration** : DADMAC (75% active);  $2 \times 10^6$  DPM (93.3  $\mu$ Ci)  
**Contact time** : 0, 28, 56 and 84 days  
**Degradation** : 0% after 84 day(s)  
**Degradation product** : Not measured.  
**Year** : 1980  
**Method** : Monongahela sandy loam soil was oven dried and 50 grams/ flask used. Flasks were purged with nitrogen and sealed. After 45 days, half were purged again and half were flooded with 5 cc water. DADMAC (75% active;  $2 \times 10^6$  DPM (93.3  $\mu$ Ci) was added to each flask. Four replicate flasks from each treatment group were removed after 0, 28, 56 and 84 days. Flasks were extracted with  $\text{CaSO}_4$  and methanol and the methanol filtered. Radioactivity in the methanol was determined in a liquid scintillation spectrometer. Another aliquot was chromatographed by TLC to determine DADMAC.

**GLP** : No  
**Test substance** : 14C-DADMAC (75% active)

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#### Result

: The results are summarized in the following table:

Days of anaerobic conditions	Radioactivity (DPMX10 <sup>5</sup> /50 gm soil)	
	Non-Extractable	Extractable
0	6.0	1.5
1	6.0	1.5
2	6.0	1.5
7	5.9	1.6
14	6.0	1.4
21	6.1	1.5
28	6.1	1.5
56	6.1	1.4
84	6.1	1.2
112	6.1	1.0

Test substance

: 14C-DADMAC (75% active)

Conclusion

: Dried soil has little impact on DADMAC

Reliability

: (2) valid with restrictions

Acceptable, well documented report which meets basic scientific principles.

29.10.2003

(2)

Type

: Effects of microbes on metabolism.

Reference

: Reick (1980c)

Soil

: Monongahela sandy loam soil

Concentration

: DADMAC (75% active; 2X10<sup>6</sup> DPM (93.3 µCi)

Contact time

: None

Deg. product

: Not measured.

Year

: 1980

Method

: Monongahela sandy loam soil was used in this study. Soil was placed within 5 cm of the top of each tube and cheesecloth attached to one end to allow drainage. A layer of cheese cloth was placed on top of the soil. DADMAC (75% active; 6X10<sup>6</sup> DPM (280 µCi) was mixed with soil and placed on top of the last cheesecloth layer. Twenty acre inches of water were added to each column and leachate collected. After leaching, the soil was removed from the columns and sectioned into 10 2 cm sections. In the aged columns, the soil was treated uniformly and incubated "aged" for 42 days. This soil was then placed on the cheesecloth and handled as before. Soil was extracted with CaSO<sub>4</sub> and methanol and the leachate freeze dried. Both samples were analyzed in a liquid scintillation spectrometer. Flasks were extracted with CaSO<sub>4</sub> and methanol and the methanol filtered. Radioactivity in the methanol was determined in a liquid scintillation spectrometer. Another aliquot was chromatographed by TLC to determine DADMAC.

GLP

: No

Test substance

: 14C-DADMAC

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**Result** : The results are shown in the following table:

Section	Unaged Dpm/gm soil X10 <sup>2</sup>	Aged Dpm/gm soil X10 <sup>2</sup>
1	18.4	36.6
2	35.2	50.0
2	36.7	41.8
4	44.3	36.7
5	31.6	23.5
6	27.3	10.5
7	18.0	10.4
8	5.3	8.2
9	36.4	3.12
10	0.95	0.52

**Test substance** : 14C-DADMAC (75% active)  
**Conclusion** : DADMAC is more mobile than polyDADMAC  
**Reliability** : (2) valid with restrictions  
Acceptable, well documented report which meets basic scientific principles.  
29.10.2003 (3)

#### 3.6 BOD5, COD OR BOD5/COD RATIO

#### 3.7 BIOACCUMULATION

**Type** : Plant availability.  
**Year** : Reick (1980d)  
**Soil** : Monongahela sandy loam soil  
**Concentration** : DADMAC (75% active); 2X10<sup>6</sup> DPM (93.3 µCi)  
**Contact time** : 0, 2, 4 and 8 weeks  
**Year** : 1980  
**Method** : Monongahela sandy loam soil was used in this study. Both "aged" and unaged soil were used. Soil was placed in a 2 liter glass container suitable for growing plants in a greenhouse. Sediment was applied to soil at the highest level considered to be a potential use; 22,000,000 dpm/container. Seeds of 4 types of plants, corn, soybeans, carrots and spinach were planted. Plants from each type were removed 2,3,6, and 8 weeks after planting.  
**GLP** : No  
**Test substance** : 14C-DADMAC



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Result

:

UNAGED				
Plant	2 weeks dpm(weight)	4 weeks dpm(weight)	6 weeks dpm(weight)	8 weeks dpm(weight)
Spinach	678 (0.0186)	1166 (0.0237)	2174 (0.0287)	2176 (0.0266)
Carrot (root)	317 (0.0027)	3233 (0.0026)	914 (0.0021)	3267 (0.0225)
Carrot (top)	413 (0.0075)	1076 (0.0181)	1900 (0.0366)	3267 (0.0225)
Soybean (lower)	668 (0.0258)	1220 (0.0181)	2044 (0.0700)	11665 (0.0895)
Soybean (cotyledon)	2966 (0.1046)	2633 (0.0266)		
Soybean (upper)	324 (0.0432)	701 (0.1445)	1236 0.2497)	1206 (0.1925)
Corn	1934 (0.0760)	10716 (0.2112)	17017 (0.4945)	38852 (1.1824)
AGED				
Spinach	367 (0.0176)	568 (0.0145)	618 (0.0203)	1214 (0.0122)
Carrot (root)	239 (0.0043)	2717 (0.0025)	897 (0.0011)	3240 (0.0043)
Carrot (top)	95 (0.0306)	852 (0.0298)	893 (0.0449)	3699 (0.0630)
Soybean (lower)	783 (0.0306)	713 (0.0298)	1424 (0.0449)	1973 (0.0630)
Soybean (cotyledon)	772 (0.0548)	1793 (0.0425)		
Soybean (upper)	192 (0.0420)	291 (0.1296)	654 0.2127)	878 (0.3574)
Corn	1299 (0.0677)	7990 (0.1854)	10572 (0.4188)	27384 (0.9344)

**Test substance**  
**Conclusion**

- : 14C-DADMAC (75% active)  
: Uptake of radioactivity from DADMAC generally increased with time. There was more taken up from unaged than aged soil. In no case, not even corn, did the level approach 0.1%. Essentially no uptake of the 22,000,000 dpm was obtained. The low amount taken up could be due to dust or soil contamination during the greenhouse test.

**Reliability**

- : (2) valid with restrictions  
Acceptable, well documented report which meets basic scientific principles.

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(4)

#### 3.8 ADDITIONAL REMARKS

## 4. Ecotoxicity

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### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

- Type** : Static.  
**Reference** : Johnson, C. (1971).  
**Species** : Blue Gill Sunfish (*Lepomis macrochirus*) (Fish, fresh water).  
**Exposure period** : 72 hours.  
**Unit** : mg/l  
**LC0** : 56  
**LC50** : Not observed.  
**LC50** : Not observed.  
**Analytical monitoring** : No.  
**Method** : Safety Test in Bluegill Sunfish.  
**Year** : 1971  
**GLP** : No.  
**Test substance** : DADMAC (70% solution in water)  
**Concentrations** : 0, 1, 10, 18, 24, 32, 56  
**Test procedure** : Groups of 10 or 20 fresh water Blue Gill Sunfish (*Lepomis macrochirus*) were exposed in a reconstituted medium at 64° - 69°F for 96 hours. The pH was carefully monitored throughout the study. Concentrations of 0.0 (20 fish), 1.0 (10 fish), 10 (10 fish), 18 (10 fish), 24 (20 fish), 32 (20 fish), and 56.0 mg/l (10 fish) of test substance were used. Fish mortality was measured after 24, 48 and 96 hours.
- Results** : The only toxic sign observed was at 56 mg/l of DADMAC; some of the fish appeared slightly less active than the other fish in the study.

Test Concentration (mg/L)	Mortality			
	24 hours	48 hours	72 hours	96 hours
0	0/20	0/20	0/20	0/20
1	0/10	0/10	0/10	0/10
10	0/10	0/10	0/10	0/10
18	0/10	0/10	0/10	0/10
24	0/20	0/20	0/20	0/20
32	0/20	0/20	0/20	0/20
56	0/10	0/10	0/10	0/10

Since there were no mortalities the LC0 is considered to be 56 mg/l.

- Test substance** : DADMAC (70% solution in water)  
**Conclusion** : DADMAC has no lethal effects on freshwater fish at concentration up to 56 mg/l. The test substance is not of toxic concern to Blue Gill Sunfish.  
**Reliability** : (2) valid with data  
Basic data given: comparable with guidelines/standards

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(5)

### 4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

- Type** : Effect of DADMAC on Daphnids  
**Exposure period** : 48 hour  
**Unit** : mg/l (ppm)

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LC50 :  $1.57 \times 10^6$   
Method : ECOSAR  
Reliability : (2) valid with restrictions.  
Generally accepted method of calculation with restrictions.  
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### 4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

Type : Blue-Green Algae Toxicity  
Exposure period : 96 hours  
Unit : mg/L  
LC50 : 33.3  
Method : ECOSAR  
Reliability : (2) valid with restrictions.  
Generally accepted method of calculation with restrictions.  
27.10.2003

### 4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

Type : Effect on soil microbes  
Year : Reick (1980e)  
Source of Microbes : Monongahela fine sandy loam soil  
Exposure period : 3 weeks  
Unit : mg/l  
LC0 : >10  
Analytical monitoring : No  
Year : 1980  
Method : Moist soil was treated with DADMAC at the rate of 0, 1, 10 ppm. Treatment was replicated three times. Bacterium, actinomycetes, and fungi populations were determined at 0, 1, 2, and 4 weeks after initiation of treatment. One gram of soil was mixed with 99 ml distilled water to enumerate microorganisms. Dilutions were repeated until appropriate concentrations were reached.  
GLP : No  
Test substance : DADMAC (70% solution in water)  
Concentrations : 0, 1 and 10 pp  
Results : The only toxic sign observed was at 56 mg/l of DADMAC; some of the fish appeared slightly less active than the other fish in the study.

Test Concentration (mg/L)	Organism	Number (x 10 <sup>3</sup> )			
		0 weeks	1 week	2 weeks	4 weeks
0	Fungi	23	25	20	28
1		21	26	28	30
10		20	2	24	30
0	Soil Bacteria and Actinomycetes	100	80	75	78
1		100	85	75	80
10		95	90	80	80

No effect from 1 or 10 ppm DADMAC on any population of microbes, bacteria, actinomycetes or fungi was noted

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**Test substance** : DADMAC (70% solution in water)  
**Conclusion** : At the concentrations tested, DADMAC does not affect microbial activity.  
**Reliability** : (2) valid with restrictions  
Acceptable, well documented report which meets basic scientific principles.  
29.10.2003 (6)

### 4.5.1 CHRONIC TOXICITY TO FISH

### 4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

### 4.6.1 TOXICITY TO SEDIMENT DWELLING ORGANISMS

### 4.6.2 TOXICITY TO TERRESTRIAL PLANTS

### 4.6.3 TOXICITY TO SOIL DWELLING ORGANISMS

### 4.6.4 TOX. TO OTHER NON MAMM. TERR. SPECIES

### 4.7 BIOLOGICAL EFFECTS MONITORING

### 4.8 BIOTRANSFORMATION AND KINETICS

### 4.9 ADDITIONAL REMARKS

## 5. Toxicity

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### 5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION

Type	: Oral absorption, distribution and excretion.
Reference	: Easterday, O. (1965a).
Species	: Rat.
Strain	: Unspecified.
Sex	: Male and female.
Number of animals	: 3 animals per group.
Vehicle	: Water.
Doses	: 656 mg/kg (24 hours); 1585 mg/kg (48 hours); 1591 mg/kg (72 hours).
Analytical monitoring	: No.
Method	: Isotope distribution.
Year	: 1975
GLP	: No.
Method	: Male albino rats were placed in metabolism cages. Following intubation with C14 DADMAC, one animal per time point, urine and feces were collected at 24, 48 and 72 hours. Animals were treated with 656 mg/kg (24 hours); 1585 mg/kg (48 hours) or 1591 mg/kg (72 hours) of C14 DADMAC (100 microcuries/ml: 100 microcuries/1.9 grams. Purity unspecified). Carcasses were frozen and radioactivity determined later in blood, spleen, liver, kidneys, bone marrow, and three sections of gastrointestinal tract. Carcasses, after removal of skin and feet were homogenized and radioactivity determined.
Remark	: While this study has marked deficiencies, it demonstrates that DADMAC is poorly absorbed.
Test substance	: C14 DADMAC (solution in water)
Result	: No change in clinical signs was observed in the treated animals. There was a slight weight loss in the study. The primary route of excretion for C14 derived from DADMAC monomer was feces (see below).

C14 Excretion in:	Treatment (hours)		
	0 to 24 *	24 to 48	48 to 72
Urine	1.3%	0.7%	0.3%
Feces	68%	10%	0.3%
CO <sub>2</sub>	0.021%	0.033%	0.012%
*This animal received a slightly reduced dose than the other 2.			

The tissue levels for monomer were very low at each time point and there was no accumulation in any organ. The highest concentration of any organ was liver at 24 hours which had 0.0034% of the administered radioactivity.

Test substance	: DADMAC (solution in water)
Conclusion	: DADMAC was poorly absorbed. Of the tissues studied, the liver was found to have the largest percent uptake. The principle route of excretion was via the feces followed by the urinary pathway with a very low amount being excreted via the expired air. The largest elimination was observed to occur during the first 24 hours.
Reliability	: (2) valid with restrictions. Acceptable, well documented report which meets basic scientific principles but pre-dates GLP.

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(7)

## 5. Toxicity

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### 5.1.1 ACUTE ORAL TOXICITY

**Type** : Acute oral toxicity.  
**Reference** : Sterner, W (1975)  
**Value** : 3930 mg/kg bw  
**Species** : Rat.  
**Strain** : Wistar  
**Sex** : Male and female.  
**Number of animals** : 40  
**Vehicle** : Water  
**Doses** : 0, 3.18, 3.98, 5.00 and 6.30 ml/kg  
**Method** : Procter and Gamble Standard Procedure 1  
**Year** : 1975  
**GLP** : No  
**Test substance** : DADMAC (64.3% solution in water).  
**Analytical monitoring** : No.  
**Method** : Doses of DADMAC were given by gavage to 3 groups of 10 fasted Wistar rats. Doses were separated by 0.1 log units. Mortality was reported at 1 and 14 days.  
**Result** : Mortality was as follows:

Group	Dose (ml/kg)	1 day mortality	14 day mortality
I	3.18	0/10	0/10
II	3.98	1/10	1/10
III	5.00	6/10	6/10
IV	6.30	10/10	10/10

**Test substance** : DADMAC  
**Conclusion** : The oral LD50 for the 63% solution was calculated as 4.81 (4.41 - 5.53) ml/kg. The oral LD50 was 3.93 g/kg DADMAC.  
**Reliability** : (2) valid with data  
Basic data given: comparable with guidelines/standards

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(8)

**Type** : Acute oral toxicity.  
**Reference** : Easterday, O. (1965b).  
**Value** : 2520 mg/kg bw  
**Species** : Rat  
**Strain** : Sprague-Dawley  
**Sex** : Male  
**Number of animals** : 30  
**Vehicle** : Water.  
**Doses** : 31.6, 100, 316, 1000, 3160, and 10000 mg/kg.  
**Method** : Not referenced.  
**Year** : 1964  
**GLP** : No  
**Test substance** : White solid.  
**Analytical monitoring** : No.  
**Method** : Groups of 5 fasting male albino Sprague-Dawley rats were treated by gavage with 31.6, 100, 316, 1000, 3160, and 10000 mg/kg representing a spread of 0.3 log units. Rats were observed for 14 days

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**Result** : Mortality was as follows:

Dose mg/kg	Conc. of solution (%)	1 hour	4 hours	24 hours	2 days	3 days	14 days
31.6	1.0	0/5	0/5	0/5	0/5	0/5	0/5
100	1.0	0/5	0/5	0/5	0/5	0/5	0/5
316	10	0/5	0/5	0/5	0/5	0/5	0/5
1,000	10	0/5	0/5	0/5	0/5	0/5	0/5
3,160	40	0/5	0/5	3/5	3/5	3/5	3/5
10,000	40	0/5	1/5	4/5	5/5	5/5	5/5

**Test substance** : DADMAC.

**Conclusion** : The acute oral LD50 of DADMAC in rats at 14 days was 2520 (1600 - 4950) mg/kg

**Reliability** : (2) valid with data

Basic data given: comparable with guidelines/standards

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(9)

### 5.1.2 ACUTE INHALATION TOXICITY

### 5.1.3 ACUTE DERMAL TOXICITY

### 5.1.4 ACUTE TOXICITY, OTHER ROUTES

### 5.2.1 SKIN IRRITATION

**Type** : Primary skin irritation and corrosivity.  
**Reference** : Vinegar, M. (1978).  
**Species** : Rabbit  
**Strain** : New Zealand White  
**Concentration** : Test material as supplied.  
**Exposure** : Back and abdomen, intact and abraded skin; saddle, intact skin  
**Exposure time** : 24 hours (Irritation); 4 hours (Corrosivity).  
**Number of animals** : 6 per test.  
**Vehicle** : None.  
**PDII (dorsal)** : <0.1 (dorsal = 0.09; ventral = 0.04)  
**Method** : Patch Test for Primary Skin Irritation and Corrosivity (Code of Federal Regulations, Title 16, Chapter II, 1976) and Section 173.240 of the department of Transportation Hazardous Materials Regulations ( Federal Register, Monday, September 27, 1976).  
**Year** : 1978  
**GLP** : No.  
**Test substance** : CC-47 DADMAC MONOMER  
**Testing system** : Primary Skin Irritation Test (FHSA): 0.5 ml of undiluted test material was applied under a one inch square surgical gauze patch to an intact and abraded skin on both the back and abdomen of 6 New Zealand White rabbits. Each patch was held in place by 2 one inch strips of adhesive tape. After application of the patches, the trunk of each rabbit was wrapped with

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	<p>rubber dental damming which was secured with staples. After 24 hours, the patches were removed and any residual material was removed. The reactions were scored immediately after the removal of the patches (24-hour reading) and again 48 hours later (72-hour reading). <u>Corrosivity Test (DOT)</u>: 0.5 ml of undiluted test material was applied under a one inch square surgical gauze patch to 2 intact areas of skin on each of 6 New Zealand White rabbits. The application sites were prepared by clipping the hair from the saddle areas of the rabbits. Each patch was held in place by 2 one inch strips of adhesive tape. After application of the patches, the trunk of each rabbit was wrapped with rubber dental damming which was secured with staples. The animals were secured in Newmann harnesses for 4 hours. After 4 hours, the patches were removed and any residual material was removed. The reactions were scored immediately after the removal of the patches (4-hour reading) and again at 24 and 48 hours after initial application.</p>
<b>Result</b>	: <u>Primary Skin Irritation Test</u> : Following dorsal application, irritative effects noted at the 24-hour reading included very slight erythema at one intact and one abraded site. The Primary Irritation Index (PII) was found to be 0.09. Following ventral application, no irritative effects were noted at the 24-hour reading. However, at the 72-hour reading, very slight erythema was noted at one abraded site. No other irritative effects were noted at any time throughout the study. The Primary Irritation Index (PII) was found to be 0.04. <u>Corrosivity Test</u> : Following patch application, no irritative effects were noted at any time throughout the study
<b>Test substance</b>	: DADMAC (solution of unknown concentration).
<b>Conclusion</b>	: DADMAC was determined to be not irritating to skin in this assay.
<b>Reliability</b>	: (1) valid without restrictions
	Guideline study.
28.10.2003	(10)

### 5.2.2 EYE IRRITATION

<b>Species</b>	: Acute eye irritation.
<b>Reference</b>	: Vinegar, M. (1978).
<b>Species</b>	: Rabbit.
<b>Strain</b>	: New Zealand White.
<b>Concentration</b>	: Test material as supplied.
<b>Dose</b>	: 0.1 ml
<b>Exposure time</b>	: 72 hours.
<b>Number of animals</b>	: 6
<b>Vehicle</b>	: None.
<b>Result</b>	: Not irritating
<b>Method</b>	: Acute Eye Irritation (Code of Federal Regulations, Title 16, Chapter II, 1976)
<b>Year</b>	: 1978
<b>GLP</b>	: No.
<b>Test substance</b>	: CC-47 DADMAC MONOMER
<b>System of testing</b>	: 0.1 ml of the undiluted sample was applied to the right eye of each of 6 New Zealand White rabbits. The left eyes were untreated and served as controls. Examinations for gross signs of eye irritation were made at 24, 48 and 72 hours following application. Scoring of the irritative effects was made according to the method of Draize.
<b>Result</b>	: Irritative effects noted at the 24-hour reading following application included slight to moderate conjunctival erythema and slight conjunctival discharge in 3 rabbits. At the 48-hour reading slight to moderate conjunctival erythema was noted in 3 rabbits. At the 72-hour reading slight conjunctival erythema was



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Test substance : noted in 1 rabbit. No corneal opacity or iritis was noted.  
Conclusion : DADMAC (solution of unknown concentration)  
Reliability : DADMAC was determined to be not irritating to eyes in this assay.  
: (1) valid without restrictions.  
Guideline study.

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(10)

### 5.3 SENSITIZATION

### 5.4 REPEATED DOSE TOXICITY

Type : 13-week oral toxicity feeding study.  
Reference : Tegeris, A. (1976).  
Species : Dog.  
Sex : Male & female.  
Strain : Beagle.  
Route of admin. : Oral, feed.  
Exposure period : 90 days  
Frequency of treatm. : Daily.  
Post exposure period : None.  
Doses : 50, 200, 800 mg/kg/day  
Control group : Yes, concurrent, no treatment.  
NOAEL : = 200 mg/kg/day  
LOAEL : = 800 mg/kg/day  
Method : 13 Week Oral Toxicity Feeding Study in Dogs.  
Year : 1976  
GLP : No (study was performed to FIFRA guidelines).  
Method : Groups of 4 male and 4 female purebred beagle dogs, averaging 3 to 4 months old, were fed diets containing 50, 200, or 800 mg/kg/day of DADMAC monomer. Diets were adjusted to deliver specified doses of monomer in a 350 gram meal. The dogs were carefully observed for 13 weeks. Samples were taken for clinical chemistry and hematology at 45 days and at termination. All dogs were necropsied and histopathology performed.  
  
Result : At 800 mg/kg/day, there was a decrease in body weight gain. Otherwise there were no treatment related effects in this study. The NOAEL was 200 mg/kg/day.  
  
Test substance : DADMAC (45% solution in water).  
Conclusion : The NOAEL for this study is 200 mg/kg/day.  
Reliability : (1) valid without restrictions  
Guideline study.

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(11)

Type : 13-week oral toxicity feeding study.  
Reference : Sterner, W. (1976).  
Species : Rat.  
Sex : Male & female.  
Strain : Unspecified.  
Route of admin. : Oral, feed  
Exposure period : 90 days.  
Frequency of treatm. : Daily.  
Post exposure period : None  
Doses : 5, 50, 500 mg/kg/day  
Control group : Yes, concurrent, no treatment

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NOAEL	:	= 50 mg/kg/day
LOAEL	:	= 500 mg/kg/day
Method	:	13-Week Oral Toxicity Feeding Study in Rats
Year	:	1976
GLP	:	No.
Method	:	Groups of 15 male and 15 female rats of unspecified strain were fed diets containing 5, 50 or 500 mg/kg of DADMAC monomer. 5 animals per group were sacrificed at 4, 8 and 13 weeks for histopathology.
Result	:	In the high dose group, a significant decrease in body weight gain was observed. No significant treatment related histopathology was observed in this study. The NOAEL was determined to be 50 mg/kg/day based on body weight gain. A hexibarbitone sleeping time study was included in this study to assess drug metabolizing enzymes. There was no treatment related effect on hexabarbitone sleeping time.
Test substance	:	DADMAC
Conclusion	:	The NOAEL for this study is 50 mg/kg/day.
Reliability	:	(3) not reliable. Insufficient documentation for assessment.
29.10.2003		(12)

### 5.5 GENETIC TOXICITY 'IN VITRO'

Type	:	Ames test.
Reference	:	San, R. (1991).
System of testing	:	Salmonella microsome plate test.
Test concentration	:	167, 500, 1670, 5,000, 7,500, and 10,000 µg/plate in the presence/absence of S9.
Cytotoxic conc.	:	No cytotoxicity was observed in this study.
Metabolic activation	:	With and without
Result	:	Negative.
Method	:	As described in Ames (1975) and Maron (1983).
Year	:	1991
GLP	:	Yes.
Method	:	The test compound was evaluated in triplicate cultures in strains TA1535, TA1537, TA1538, TA98 and TA100 in the presence and absence of S9 at the above doses. (Ames <i>et al</i> , 1975)
Result	:	The ratio of revertants in treated plates versus controls never exceeded 1.4. No significant increase in mutations either in presence or absence of S-9
Test substance	:	DADMAC (solution in water).
Conclusion	:	Under the experimental conditions, the test substance (DADMAC) did not show mutagenic activity in this bacterial reverse mutation test of <i>Salmonella typhimurium</i> .
Reliability	:	(1) valid without restrictions Guideline study.
27.10.2003		(13)

Type	:	Ames test
Reference	:	De Jouffrey (1996a).
System of testing	:	Salmonella microsome plate test.
Test concentration	:	312.5, 626, 1,250, 2,500 and 5,000 µg/plate in the presence/absence of S9.
Cycotoxic conc.	:	No increase in mutations in presence or absence of S-9.
Metabolic activation	:	With and without.
Result	:	Negative.
Method	:	OECD Guidelines for the Testing of Chemicals, Guideline No. 471, May 1983 (revised September, 1995): "Genetic Toxicology: <i>Salmonella Typhimurium</i> Reverse Mutation Assay".

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**Year** : 1996.  
**GLP** : Yes.  
**Method** : The test compound was evaluated in triplicate cultures in strains TA1535, TA1537, TA1538, TA98 and TA100 in the presence and absence of S9 at doses of 312.5, 626, 1,250, 2,500 and 5,000 µg/plate.  
**Result** : Revertant frequencies for all doses of the test compound in all strains with and without S9 approximated or were less than those observed in the concurrent negative control cultures. All positive and negative control values were within acceptable limits.  
**Test substance** : DADMAC (50% solution in water).  
**Conclusion** : Under the experimental conditions, the test substance (DADMAC) did not show mutagenic activity in this bacterial reverse mutation test of *Salmonella typhimurium*.  
**Reliability** : (1) valid without restrictions.  
Guideline study.

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(14)

**Type** : Mammalian cell gene mutation assay.  
**Reference** : De Jouffrey (1996b).  
**System of testing** : Mouse lymphoma (TK<sup>+/+</sup>) L5178Y cells  
**Test concentration** : 625, 1,250, 2,500 and 5000 µg/plate.  
**Metabolic activation** : With and without.  
**Result** : Negative.  
**Method** : OECD Guidelines for the Testing of Chemicals, Number 476, April 4, 1984: "Genetic Toxicology: *In Vitro* Mammalian Cell Gene Mutation Test"  
**Year** : 1996.  
**GLP** : Yes.  
**Method** : Cells were suspended in medium with test article in the presence or absence of S9 metabolic activation for 4 hours. Article was removed by centrifugation and cells washed twice. Cells were plated to determine cell density (cloning efficiency). Cells were selected in the presence of 100 µg/ml TFT after 14 days.  
**Result** : The highest concentration applied produced a decrease of cell culture growth and the cell growth observed at the lowest concentration was approximately in the range of the negative control. No precipitation of test article was observed. No substantial and reproducible increase in mutant colony numbers was observed at any valuated concentration neither in the presence or absence of metabolic activation. Furthermore, there was no indication of a dose-dependant increase in the number of spontaneous mutant colonies in the solvent control. The results of this study are shown below:

Concentration (mg/ml)	S-9	Viability % Survival	Mutant Frequency per 10 <sup>6</sup> Survivors
0.00	—	100	53
	+	100	75
0.625	—	105	66
	+	103	62
1.25	—	74	68
	+	103	80
2.50	—	83	63
	+	103	80
5.00	—	89	57
	+	120	54
MMS	—	50	506
CPA	+	61	853

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The material did not significantly increase the mutant frequency in this test.

<b>Test substance</b>	: DADMAC (50% solution in water)
<b>Conclusion</b>	: Under the experimental conditions, the test substance (DADMAC) did not show mutagenic activity in mouse lymphoma cells in the presence or absence of S9 metabolic activation.
<b>Reliability</b>	: (1) valid without restrictions. Guideline study.
28.10.2003	(15)
<b>Type</b>	: Cytogenetic assay.
<b>Reference</b>	: De Jouffrey (1996c)
<b>System of testing</b>	: Human lymphocytes.
<b>Test concentration</b>	: 1,250, 2,500 and 5,000 µg/plate
<b>Metabolic activation</b>	: With and without.
<b>Result</b>	: Negative.
<b>Method</b>	: OECD Guidelines for the Testing of Chemicals, Number 473, May 26, 1983 (revised draft September, 1995): "Genetic Toxicology: <i>In Vitro</i> Mammalian Cytogenetic Test".
<b>Year</b>	: 1996
<b>GLP</b>	: Yes.
<b>Method</b>	: Human blood was collected, washed 3 times and suspended at a concentration of $1 \times 10^6$ cells. 5ml-aliquots were incubated at 37°C for 48 hours. Test compound was added to give final concentration of 625, 1250, 2,500 and 5,000 µg/ml (positive and negative controls were used). For metabolic activation 1.25 ml S9 was added to each culture. Cultures were incubated for 24 hours (2 hour exposure). Colchicine was added to each culture. After 2 hours, cells were centrifuged, collected and fixed. Slides were stained using Giemsa solution. Metaphase figures were identified and chromosomes analyzed.
<b>Result</b>	: No significant increase in chromosomal damage was seen at any dose tested. No compound-related effect was seen in the presence of metabolic activation.
<b>Test substance</b>	: DADMAC (50% solution in water).
<b>Conclusion</b>	: Under the experimental conditions, the test substance (DADMAC) was not clastogenic in human lymphocytes.
<b>Reliability</b>	: (1) valid without restrictions Guideline study.
29.10.2003	(16)

### 5.6 GENETIC TOXICITY 'IN VIVO'

<b>Type</b>	: Mammalian cell gene mutation assay.
<b>Reference</b>	: Putman, D. (1991).
<b>Species</b>	: Mice.
<b>Strain</b>	: ICR.
<b>System of testing</b>	: Bone marrow erythrocytes..
<b>Test concentration</b>	: 22, 43 or 85 mg/kg
<b>Control group</b>	: Yes, negative and positive
<b>Result</b>	: Negative.
<b>Carrier</b>	: Water.
<b>Method</b>	: A rapid <i>in vivo</i> test for chromosomal damage (Heddle, 1973)
<b>Year</b>	: 1991
<b>GLP</b>	: Yes.

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<b>System of testing</b>	: Male and female ICR mice were exposed to 22, 43 or 85 mg/kg of Diallyldimethylammonium chloride (DADMAC), which was administered at a constant rate of 10 ml/kg as a single IP injection. The high dose level was calculated to be 80% of the LD50. Bone marrow cells, collected at 24, 48 and 72 hours after treatment, were examined microscopically for micronucleated, polychromatic erythrocytes.
<b>Result</b>	: No change in the ratio of polychromatic erythrocytes to total erythrocytes was observed in the male or female mice in the test article treated groups suggesting the test article did not induce bone marrow toxicity. No significant increase in polynucleated, polychromatic ethrocytes were observed at 24, 48 or 96 hours after dose administration in males or females.
<b>Test substance</b>	: DADMAC (solution in water)
<b>Conclusion</b>	: Under the experimental conditions, the test substance (DADMAC) did not increase the incidence of micronuclei in mouse bone marrow.
<b>Reliability</b>	: (1) valid without restrictions Guideline study.

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### 5.7 CARCINOGENICITY

#### 5.8.1 TOXICITY TO FERTILITY

<b>Type</b>	Multigeneration reproduction study in rats.
<b>Reference</b>	Adamik, E. (1979).
<b>Species</b>	: Rat.
<b>Strain</b>	Sprague-Dawley.
<b>Sex</b>	: Male and female.
<b>Number of animals</b>	: 10 male and 20 female per dose group, 4 dose groups.
<b>Method</b>	National Academy of Sciences Guidelines: Principles and Procedures for Evaluating the Toxicity of Household Substances, Assembly of Life Sciences, National research Council, Prepared for the National Academy of Sciences.
<b>GLP</b>	No.
<b>Year</b>	1979.
<b>Route of admin</b>	Oral; gavage
<b>Test substance</b>	Homopolymer of DADMAC (polyDADMAC), 20% in solution in water containing at least 1% residual DADMAC monomer.
<b>Doses</b>	: 0, 0.375, 12.5 and 125 mg/kg polyDADMAC corresponding to at least 0.00375, 0.125, and 1.25 mg/kg DADMAC.
<b>Vehicle</b>	: Water.
<b>Control group reatm.</b>	: 1.0 ml/kg deionized water; gavage.
<b>Frequency of treatm.</b>	: Daily.
<b>Duration of test</b>	: 133 days, F <sub>0</sub> (male & female) = 8 weeks; F <sub>1</sub> = 27 weeks;
<b>Pre-mating exposure</b>	None.
<b>Statistical methods</b>	No statistical analyses were performed. All parameters were within the normal limits for all groups.

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### Test conditions

Each male was mated with 2 females.  $F_0$  animals (male and female) were treated from day of mating to weaning of the  $F_1$  pups. The  $F_1$  generation was treated from 21 days of age through weaning of the  $F_{2b}$  generation. Males were mated with one female until appearance of the copulatory plug. If a plug was not observed within 5 days the female was mated with another male of the same treatment group. At weaning, 10 males and 20 females were randomly selected from each group to later become the  $F_1$  parental generation. When the  $F_1$  animals became sexually mature (40-50 days of age), each male was mated with 2 females of the same treatment group. Selection of mating males and females from the same litter was avoided. If a plug was not noted through 2 estrous cycles (10 days), another male from the same treatment group was placed with the female. When the  $F_1$  generation produced the  $F_{2a}$  generation, the litters were weaned at 21 days *post partum* and killed. After an appropriate 15-day rest period, the  $F_1$  generation was mated again. Litters in excess of 10 rats were culled to 10 rats.

The following reproductive parameters were assessed during the study:

Parental generation: Live weight, duration of gestation, evidence of difficult or prolonged labor, maternal neglect and agalactia.

Litters: Total offspring at birth, number and sex of dead at birth, number and sex of abnormal at birth, viable offspring at days 4,7,14 and 21, live weight of litters, viable offspring and sex at birth, 4,7,14 and 21 days.

Gross pathology: Any pup from  $F_1$ ,  $F_{2a}$  or  $F_{2b}$  generations appearing abnormal. One normal male and one normal female from each litter was subjected to gross pathology.

Microscopic pathology: Reproductive organs from 10 rats/sex from control and high dose groups were examined.

Other parameters were assessed during the study: Weight gain and clinical signs.

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### Results

NOAEL for P is 1.25 mg/kg DADMAC (125 mg/kg polyDADMAC).  
NOAEL for F<sub>1</sub> is 1.25 mg/kg DADMAC (125 mg/kg polyDADMAC).  
NOAEL for F<sub>2</sub> is 1.25 mg/kg DADMAC (125 mg/kg polyDADMAC).

There were no effects on maternal body weights, pup body weights, litter size, mating index, fecundity index, male fertility index, female fertility index, incidence of parturition, live birth and survival indices. The table below summarizes the results.

Dose (mg/kg)*	F <sub>0</sub>		F <sub>1a</sub>		F <sub>1b</sub>	
	Fertility index	Parturition Index	Fertility index	Parturition Index	Fertility index	Parturition Index
0.00	17/20	100%	17/19	100%	18/19	100%
0.00375	17/20	100%	119/20	100%	18/20	100%
0.125	18/20	100%	18/20	100%	19/20	100%
1.25	16/20	100%	18/19	100%	18/19	100%

\* mg/kg DADMAC based on 1% residual monomer in the polyDADMAC product.

There was no compound related on F<sub>2a</sub> and F<sub>2b</sub> generation pup body weights. There was also no compound related effects on the number of live births, still births, total litter size, nor any effect on maternal instinct and raising of the pups. There was no compound related mating index, fecundity index, male fertility index, female fertility index, incidence of parturition, live birth and survival indices. No remarkable pathology was noted amongst female F<sub>1</sub> and F<sub>2</sub> animals. Mottled kidneys were found in F<sub>1</sub> but not F<sub>2</sub> males.

### Test substance Conclusions

: DADMAC homopolymer (20% solution in water) containing ≥ 1% DADMAC. The test (polyDADMAC) material produced no increase in the reproductive failure as compared to control group when dosed orally to rats at dose levels of 0.375, 12.5 and 125 mg/kg/day throughout 2 generations. No compound related effect upon fertility index or any other parameters evaluated was observed. Based on a minimum residual DADMAC monomer concentration of 1% by weight, the No Observed Adverse Effect Level (NOAEL) for DADMAC is 1.25 mg/kg/day.

### Reliability

(1) valid without restrictions.  
Guideline study.

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### 5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

#### Type Reference Species Sex Strain Number of animals Method

Rat teratology study.

Palmer, K. (1991).

: Rat.

: Female

: Sprague-Dawley.

: 24 per dose group, 5 dose groups.

National Academy of Sciences Guidelines: Principles and Procedures for Evaluating the Toxicity of Household Substances, Assembly of Life Sciences, National research Council, Prepared for the National Academy of Sciences.

#### Route of admin.

: Oral, gavage.

#### Test substance

Homopolymer of DADMAC (polyDADMAC), 30% in solution in water

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<b>Doses</b>	: containing at least 1% residual DADMAC monomer. 50, 150, 450 and 600 mg/kg polyDADMAC corresponding to at least 0.5, 1.5, 4.5 and 6 mg/kg DADMAC.
<b>Exposure period</b>	: Gestational days 6 to 15.
<b>Frequency of treatm.</b>	: Daily.
<b>Duration of test</b>	: Gestational Days 0 to 20.
<b>Control group</b>	: Yes, concurrent vehicle.
<b>NOAEL maternal tox.</b>	: = 6 mg DADMAC/kg bw (600 mg polyDADMAC/kg bw).
<b>NOAEL Embryotoxicity</b>	: = 6 mg DADMAC/kg bw (600 mg polyDADMAC/kg bw).
<b>NOAEL Fetotoxicity</b>	: = 6 mg DADMAC/kg bw (600 mg polyDADMAC/kg bw).
<b>GLP</b>	: Yes.
<b>Year</b>	: 1991
<b>Method</b>	: PolyDADMAC was administered by gavage once daily on gestational days (gd) 6-15, at doses of 50, 150, 450 and 600 mg/kg (corresponding to doses of 0.5, 1.5, 4.5 and 6.0 mg/kg DADMAC). There were 24 time-mated females per group. Clinical observations were made daily except during the dosing period where they were made twice daily. Maternal body weights were monitored and food consumption was measured. At scheduled sacrifice on gd 20, the dams were evaluated for gravid uterus weight, numbers of <i>corpora lutea</i> , and live and dead fetuses were determined. Fetuses were analyzed for skeletal anomalies and malformations.
<b>Result</b>	: There was no compound related effect on body weight or body weight gain. Food consumption was significantly suppressed on days 6 through 11. Otherwise, all measured maternal parameters were normal. With regard to fetuses, their weight and sex were similar to control and no compound related malformations or anomalies observed.
<b>Test substance</b>	: DADMAC homopolymer (30% solution in water) containing $\geq 1\%$ DADMAC.
<b>Conclusion</b>	: The No Adverse Effect Level (NOAEL) of polyDADMAC in this study was the highest dose tested, i.e., 600 mg/kg/day. Based on a residual concentration of 1% DADMAC in the test material, the NOAEL for DADMAC for embryonic development is 6 mg/kg/day.
<b>Reliability</b>	: (1) valid without restrictions Guideline study.

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### 5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES

### 5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES

### 5.9 SPECIFIC INVESTIGATIONS

### 5.10 EXPOSURE EXPERIENCE

### 5.11 ADDITIONAL REMARKS



**6.1 ANALYTICAL METHODS**

**6.2 DETECTION AND IDENTIFICATION**

## **7. Eff. Against Target Org. and Intended Uses**

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### **7.1 FUNCTION**

### **7.2 EFFECTS ON ORGANISMS TO BE CONTROLLED**

### **7.3 ORGANISMS TO BE PROTECTED**

### **7.4 USER**

### **7.5 RESISTANCE**

### 8.1 METHODS HANDLING AND STORING

Avoid all contact with the product by ingestion, inhalation or contact with the skin, eyes and clothing. Do not breathe vapors or spray mist. Wash hands and face before breaks and immediately after handling the product. When using, do not smoke. Handle in accordance with good industrial hygiene and safety practice.

Store in contact with air. Do not exceed storage temperature of 30°C. Protect from light.

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### 8.2 FIRE GUIDANCE

This product does not burn in aqueous solution. No special precautions are required. In case of fire, wear a self contained breathing apparatus. Keep containers cool during fire with water spray.

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### 8.3 EMERGENCY MEASURES

If product is inhaled, move to fresh air.

In case of skin contact, rinse and wash contaminated clothing before re-use. Wash contaminated area immediately for at least 15 minutes. In case of persistent skin irritation, consult a physician.

In case of eye contact, rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing and lift upper and lower lids to ensure complete removal of chemical. In case of persistent eye irritation, consult a physician.

If swallowed, do not induce vomiting. Rinse mouth (never give anything by mouth to an unconscious person). Call a physician immediately.

In case of accidental release, do not allow product to enter drains. Do not contaminate water. Dam up spills. Soak with inert absorbent material. If liquid has been spilled in large quantities, clean up promptly by scoop or vacuum. Keep in suitable and closed containers for disposal. After cleaning, flush area with water.

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### 8.4 POSSIB. OF RENDERING SUBST. HARMLESS

Not applicable.

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### 8.5 WASTE MANAGEMENT

Can be land filled or incinerated when in compliance with local regulations.

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### 8.6 SIDE-EFFECTS DETECTION

### 8.7 SUBSTANCE REGISTERED AS DANGEROUS FOR GROUND WATER

**8.8 REACTIVITY TOWARDS CONTAINER MATERIAL**

## 9. References

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### 10.1 END POINT SUMMARY

### 10.2 HAZARD SUMMARY

### 10.3 RISK ASSESSMENT